



ATTORNEY'S DOCKET NO: C1040/7006

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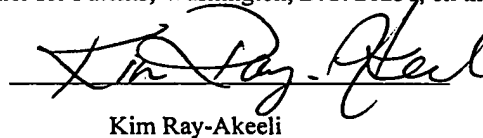
Applicant: McCluskie al.  
Serial No: 09/316,199  
Filed: May 21, 1999  
For: METHODS AND PRODUCTS FOR INDUCING MUCOSAL IMMUNITY  
Examiner: Unassigned  
Art Unit: Unassigned

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231, on the 10th day of November, 1999.

  
Kim Ray-Akeeli

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Assistant Commissioner for Patents  
Washington, D.C. 20231

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicants request consideration of this Information Disclosure Statement.

**Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

**Information Cited**

The Applicants hereby make of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicants hereby make the following additional information of record in the above-identified application:

The following are related pending U.S. non-provisional applications which do not appear on the 1449 form.

<u>Serial No.</u>	<u>Filing Date</u>
08/386,063	02/07/95
08/738,652	10/30/96
08/960,774	10/30/97
09/030,701	02/25/98
09/082,649	05/20/98
09/146,072	09/02/98
09/241,653	02/02/99
09/286,098	04/02/99
09/306,281	05/06/99
09/325,193	06/03/99
09/337,584	06/21/99
09/337,619	06/21/99
09/337,636	06/21/99
09/361,575	07/27/99

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The following are related PCT Publications, published after the priority date (copies are enclosed (B14-B17 on Form 1449)):

WO 98/37919	09/03/98
WO 98/18810	05/07/98
WO 98/40100	09/17/98
WO 98/52581	11/26/98

#### Remarks

A copy of each of the above-identified information is enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicants make no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

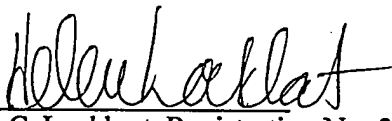
By submitting this Information Disclosure Statement, the Applicants make no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicants make no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

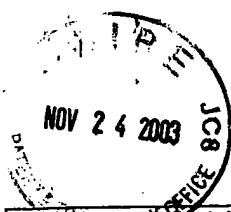
Notwithstanding any statements by the Applicants, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

By:   
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Docket No. C1040/7006  
Dated: November 10, 1999  
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FORM PTO-1449 (Modified)	ATTY. DOCKET NO.  C1040/7006	SERIAL NO.  09/316,199
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LIST OF PATENTS AND  
PUBLICATIONS FOR APPLICANT'S  
INFORMATION DISCLOSURE  
STATEMENT

APPLICANT McCluskie et al.

FILING DATE May 21, 1999

GROUP

U.S. PATENT DOCUMENTS

Exam Init	Ref Des	Document No.	Date	Name	Class	Sub Class	FILING DATE If Appropriate
	A1	3,906,092	09/16/75	Hilleman et al.			
	A2	5,248,670	09/28/93	Draper et al.	514	44	
	A3	5,585,479	12/17/96	Hoke et al.	536	24.5	
	A4	5,663,153	09/02/97	Hutcherson et al.	514	44	
	A5	5,786,189	07/28/98	Locht et al.	435	172.3	
	A6	5,849,719	12/15/98	Carson et al.	514	44	
	A7	5,723,335	03/03/98	Hutcherson, et al.	435	375	

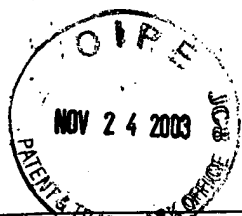
FOREIGN PATENT DOCUMENTS

		Country & Doc. No. (11)	Pub. Date (43)		Class	Sub Class	Translation Yes      No	
	B1	WO 91/12811	09/05/91	PCT	A61K	31/70		
	B2	0468520	01/29/92	EPO	A61K	31/70		
	B3	WO 92/03456	03/05/92	PCT	C07H	15/12		
	B4	WO 92/18522	10/29/92	PCT	C07H	21/00		
	B5	WO 92/21353	12/10/92	PCT	A61K	31/70		
	B6	0302758 B1	03/16/94	EPO	C12N	15/37		
	B7	WO 94/19945	09/15/94	PCT	A01N	43/04		
	B8	WO 95/05853	03/02/95	Regents of the University of CA				
	B9	WO 95/26204	10/95	PCT	A61K	48/00		
	B10	WO 96/02555	02/01/96	PCT				
	B11	WO 96/35782	11/14/96	Applied Research Systems				
	B12	WO 97/28259	08/07/97	PCT	C12N	15/00		
	B13	WO 98/18810	05/07/98	PCT	C07H	21/00		
	B14	WO 98/37919	09/03/98	PCT	A61K	49/00		
	B15	WO 98/40100	09/17/98	PCT	A61K	39/39		
	B16	WO 98/52581	11/26/98	PCT	A61K	35/00		
	B17	WO 98/14210	04/09/98	PCT	A61K	39/35		

OTHER ART

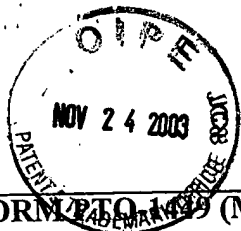
(Including Author, Title, Date, Pertinent Pages, Publication, Etc.)

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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		APPLICANT McCluskie et al.	
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C4	Azuma, Biochemical and Immunological Studies on Cellular Components of Tubercle Bacilli, <i>Kekkaku</i> , Vol. 9, 9:45-55, 1992.		
C5	Ballas ZK et al., Induction of NK activity in murine and human cells by CpG motifs in oligodeoxynucleotides and bacterial DNA. <i>J Immunol</i> 157(5):1840-5, 1996.		
C6	Bayever, E., Systemic Administration of a Phosphorothioate Oligonucleotide with a Sequence Complementary to p53 for Acute Myelogenous leukemia and Myelodysplastic Syndrome: Initial Results of a Phase I Trial, <i>Antisense Res. &amp; Dev.</i> (1993), 3:383-390.		
C7	Bennett RM et al., DNA binding to human leukocytes. Evidence for a receptor-mediated association, internalization, and degradation of DNA. <i>J Clin Invest</i> 76(6):2182-90, 1985.		
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C24	D'Andrea A et al., Interleukin 10 (IL-10) inhibits human lymphocyte interferon gamma-production by suppressing natural killer cell stimulatory factor/IL-12 synthesis in accessory cells. <i>J Exp Med</i> 178(3):1041-8, 1993.		

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FORM PTO 1009 (Modified)		ATTY. DOCKET NO.	SERIAL NO.
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		C1040/7006	09/316,199
		APPLICANT McCluskie et al.	
		FILING DATE May 21, 1999	GROUP
C25	Daheshia M et al., Immune induction and modulation by topical ocular administration of plasmid DNA encoding Antigens and cytokines, <i>Vaccine</i> , Vol. 16, No. 11/12, pp. 1103-1110, 1998.		
C26	Daynes RA et al., Induction of Common Mucosal Immunity by Hormonally Immunomodulated Peripheral Immunization, <i>Infection and Immunity</i> , Vol. 64, No. 4, pp. 1100-1109, Apr. 1996.		
C27	Englisch et al., Chemically Modified Oligonucleotides as Probes and Inhibitors, <i>Angew. Chem. Int. Ed. Engl.</i> 30:613-629, 1991.		
C28	Erb KJ et al., Infection of mice with Mycobacterium bovis-Bacillus Calmette-Guerin (BCG) suppresses allergen-induced airway eosinophilia. <i>J Exp Med</i> 187(4):561-9, 16 Feb 1998.		
C29	Etlinjer, Carrier sequence selection - one key to successful vaccines, <i>Immunology Today</i> , Vol. 13, 2:52-55, 1992.		
C30	Fox RI, Mechanism of action of hydroxychloroquine as an antirheumatic drug. <i>Chemical Abstracts</i> , 120:15, Abstract No. 182630 (April 29, 1994).		
C31	Gordon et al., Safety, Immunogenicity, and Efficacy of a Recombinantly Produced <i>Plasmodium falciparum</i> Circumsporozoite Protein-Hepatitis B Surface Antigen Subunit Vaccine, <i>JID</i> , 171, pp. 1576-1585, June 1995.		
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C33	Hadden J et al., Immunostimulants. <i>TIPS</i> , (1993), 141:169-174.		
C34	Hadden J et al., Immunopharmacology, <i>JAMA</i> , (1992) 268:20:2964-2969.		
C35	Halpern MD et al., Bacterial DNA induces murine interferon-gamma production by stimulation of interleukin-12 and tumor necrosis factor-alpha. <i>Cell Immunol</i> 167(1):72-8, 1996.		
C36	Hatzfeld J., Release of Early Human Hematopoietic Progenitors from Quiescence by Antisense Transforming Growth Factor $\beta$ 1 or Rb Oligonucleotides, <i>J. Exp. Med.</i> , (1991) 174:925-929.		
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C41	Iguchi-Aruga SM and Shaffner W, CpG methylation of the cAMP-responsive enhancer/promoter sequence TGACGTCA abolishes specific factor binding as well as transcriptional activation. <i>Genes Dev</i> 3(5):612-9, May 1989.		
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C43	Ishikawa R et al., IFN induction and associated changes in splenic leukocyte distribution. <i>J Immunol</i> 150(9):3713-27, 1 May 1993		
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 <b>FORM PTO-1449 (Modified)</b> <b>LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b>		<b>ATTY. DOCKET NO.</b>  <b>C1040/7006</b>	<b>SERIAL NO.</b>  <b>09/316,199</b>
		<b>APPLICANT McCluskie et al.</b>	
		<b>FILING DATE May 21, 1999</b>	<b>GROUP</b>
C50	Kline JN et al., CpG oligonucleotides can reverse as well as prevent Th2-mediated inflammation in a murine model of asthma. <i>J Invest Med</i> 45(7):298A, 1997.		
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C62	Krieg AM et al., "A Role for Endogenous Retroviral Sequences in the Regulation of Lymphocyte Activation, the <i>Journal of Immunology</i> , Vol. 143, 2448-2451.		
C63	Krieg AM et al., Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs, <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 95, pp. 12631-12636, October 1998.		
C64	Kuramoto et al., Oligonucleotide Sequences Required for Natural Killer Cell Activation, <i>Jpn. J. Cancer Res.</i> , 83:1128-1131, November 1992.		
C65	Larsen DL et al., Coadministration of DNA Encoding Interleukin-6 and Hemagglutinin Confers Protection from Influenza Virus Challenge in Mice, <i>Journal of Virology</i> , Vol. 72, No. 2, pp. 1704-1708, Feb. 1998.		
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C71	Macfarlane DE and Manzel L, Antagonism of immunostimulatory CpG-oligodeoxynucleotides by quinacrine, chloroquine, and structurally related compounds. <i>J Immunol</i> 160(3):1122-31, Feb 1 1998.		



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<b>FORM PTO-1449 (Modified)</b>		<b>ATTY. DOCKET NO.</b>	<b>SERIAL NO.</b>
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		C1040/7006	09/316,199
		APPLICANT <b>McCluskie et al.</b>	
		FILING DATE <b>May 21, 1999</b>	GROUP
C72	Mallon et al., Comparison of antibody response by use of synthetic adjuvant system and Freund complete adjuvant in rabbits, <i>Am J Vet Res</i> , Vol. 52, No. 9, pp. 1503-1506, September 1991.		
C74	Mannino RJ et al., Lipid Matrix-Based Vaccines for Mucosal and Systemic Immunization, pp. 363-387.		
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C79	Messina et al., Stimulation of <i>in vitro</i> Murine Lymphocyte Proliferation by Bacterial DNA. <i>J. Immunol.</i> , Vol. 147, 6:1759-1764, September 15, 1991.		
C80	Mojcik, C., et al., "Administration of a Phosphorothioate Oligonucleotide Antisense Murine Endogenous Retroviral MCF env Causes Immune Effect in vivo in a Sequence-Specific Manner", <i>Clinical Immunology and Immunopathology</i> , (1993), 67:2:130-136		
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C84	<i>New England BIOLABS 1988-1989 Catalog</i>		
C85	Nyce JW and Metzger WJ, DNA antisense therapy for asthma in an animal model. <i>Nature</i> 385:721-725, 20 Feb 1997.		
C86	Okada E et al., Intranasal Immunization of a DNA Vaccine with IL-12- and Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF)-Expressing Plasmids in Liposomes Induces Strong Mucosal and Cell-Mediated Immune Responses Against HIV-1 Antigens, <i>The Journal of Immunology</i> , 159:3638-3647, 1997.		
C87	Pisetsky et al., Stimulation of Murine Lymphocyte Proliferation... Simplex Virus., <i>Life Science</i> , 54:101-107, (1994)		
C88	Pisetsky, D., "Stimulation of in vitro proliferation of murine lymphocytes by synthetic oligodeoxynucleotides", <i>Molecular Biology Reports</i> , (1993) 18:217-221		
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FORM PTO-1549 (Modified)		ATTY. DOCKET NO.	SERIAL NO.
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		C1040/7006	09/316,199
		APPLICANT McCluskie et al.	
		FILING DATE May 21, 1999	GROUP
C97	Schwartz DA et al., Endotoxin responsiveness and grain dust-induced inflammation in the lower respiratory tract. <i>Am J Physiol</i> 267(5 Pt 1):L609-17, 1994.		
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C99	Schwartz DA et al., CpG motifs in bacterial DNA cause inflammation in the lower respiratory tract. <i>J Clin Invest</i> 100(1):68-73, 1 Jul 1997.		
C100	Shirakawa T et al., The inverse association between tuberculin responses and atopic disorder. <i>Science</i> 275(5296):77-9, 3 Jan 1997.		
C101	Sin J et al., IL-12 Gene as a DNA Vaccine Adjuvant in a Herpes Mouse Model: IL-12 Enhances Th1-Type CD4+ Cell-Mediated Protective Immunity Against Herpes Simplex Virus-2 Challenge, <i>The Journal of Immunology</i> , 162:2912-2921, 1999.		
C102	Sin J et al., In Vivo Modulation of Vaccine-Induced Immune Responses toward a Th-1 Phenotype Increases Potency and Vaccine Effectiveness in a Herpes Simplex Virus Type 2 Mouse Model, <i>Journal of Virology</i> , Vol. 73, No. 1, pp. 501-509, Jan. 1999.		
C103	Sparwasser T et al., Macrophages sense pathogens via DNA motifs: induction of tumor necrosis factor-alpha-mediated shock. <i>Eur J Immunol</i> 27(7):1671-9, Jul 1997.		
C104	Stein CA et al., Oligonucleotides as inhibitors of gene expression: a review. <i>Cancer Research</i> , 48:2659-2668, 1988.		
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C110	Thoelen et al., Safety and immunogenicity of a hepatitis B vaccine formulated with a novel adjuvant system, <i>Vaccine</i> , Vol. 16, No. 17, pp. 708-714, 1998.		
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FORM PTO-1449 (Modified)		ATTY. DOCKET NO.	SERIAL NO.
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		C1040/7006	09/316,199
		APPLICANT <b>McCluskie et al.</b>	
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C125	Whalen R, DNA Vaccines for Emerging Infection Diseases: What If?, <i>Emerging Infectious Disease</i> , Vol. 2, 3:168-175, 1996.		
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C138	Zhao Q et al., Stage-specific oligonucleotide uptake in murine bone marrow B-cell precursors. <i>Blood</i> 84(11):3660-6, 1 Dec 1994.		
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EXAMINER	DATE CONSIDERED
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